

event regardless of the nature or location of the medical service provided by the outpatient treatment facility.

(v) *Patient of the facility* means any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. For the purposes of this part, the definition encompasses employees of the facility or individuals affiliated with the facility, who in the course of their duties suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.

(w) *Physician's office* means a facility that operates as the office of a physician or other health care professional (e.g., dentist, chiropractor, optometrist, nurse practitioner, school nurse offices, school clinics, employee health clinics, or free-standing care units) for the primary purpose of examination, evaluation, and treatment or referral of patients. A physician's office may be independent, a group practice, or part of a Health Maintenance Organization.

(x) [Reserved]

(y) *Remedial action* means, for the purposes of this subpart, any action other than routine maintenance or servicing, of a device where such action is necessary to prevent recurrence of a reportable event.

(z) [Reserved]

(aa)(1) *Serious injury* means an injury or illness that:

- (i) Is life-threatening;
- (ii) Results in permanent impairment of a body function or permanent damage to body structure; or
- (iii) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(2) *Permanent* means, for purposes of this subpart, irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

(bb) *Shelf life*, as required on the manufacturer's baseline report, means the maximum time a device will remain functional from the date of manufacture until it is used in patient care. Some devices have an expiration date on their labeling indicating the maximum time they can be stored before

losing their ability to perform their intended function.

(cc) [Reserved]

(dd)(1) *User facility report number* means the number that uniquely identifies each report submitted by a user facility to manufacturers and FDA. This number consists of three parts as follows:

(i) The user facility's 10-digit Health Care Financing Administration (HCFA) number (if the HCFA number has fewer than 10 digits, fill the remaining spaces with zeros);

(ii) The four-digit calendar year in which the report is submitted; and

(iii) The four-digit sequence number of the reports submitted for the year, starting with 0001. (For example, a complete number will appear as follows: 1234560000–1995–0001.)

(2) If a facility has more than one HCFA number, it must select one that will be used for all of its MDR reports. If a facility has no HCFA number, it should use all zeros in the appropriate space in its initial report (e.g., 0000000000–1995–0001) and FDA will assign a number for future use. The number assigned will be used in FDA's record of that report and in any correspondence with the user facility. All zeros should be used subsequent to the first report if the user does not receive FDA's assigned number before the next report is submitted. If a facility has multiple sites, the primary site can report centrally and use one reporting number for all sites if the primary site provides the name, address and HCFA number for each respective site.

(ee) *Work day* means Monday through Friday, excluding Federal holidays.

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, in § 803.3, paragraph (n)(4) was stayed indefinitely.

#### § 803.9 Public availability of reports.

(a) Any report, including any FDA record of a telephone report, submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter;

(2) Any personal, medical, and similar information (including the serial number of implanted devices), which would constitute an invasion of personal privacy under §20.63 of this chapter. FDA will disclose to a patient who requests a report, all the information in the report concerning that patient, as provided in §20.61 of this chapter; and

(3) Any names and other identifying information of a third party voluntarily submitting an adverse event report.

(c) FDA may not disclose the identity of a device user facility which makes a report under this part except in connection with:

(1) An action brought to enforce section 301(q) of the act, including the failure or refusal to furnish material or information required by section 519 of the act;

(2) A communication to a manufacturer of a device which is the subject of a report required by a user facility under §803.30;

(3) A disclosure relating to a manufacturer or distributor adverse event report that is required under section 519(a) of the act; or

(4) A disclosure to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

#### **§803.10 General description of reports required from user facilities and manufacturers.**

(a) *Device user facilities.* User facilities must submit the following reports, which are described more fully in subpart C of this part.

(1) User facilities must submit MDR reports of individual adverse events within 10 days after the user facility becomes aware of an MDR reportable event as described in §§803.30 and 803.32.

(i) User facilities must submit reports of device-related deaths to FDA and to the manufacturer, if known.

(ii) User facilities must submit reports of device-related serious injuries to manufacturers, or to FDA, if the manufacturer is unknown.

(2) User facilities must submit semi-annual reports as described in §803.33.

(b) [Reserved]

(c) *Device manufacturers.* Manufacturers must submit the following reports as described more fully in subpart E of this part:

(1) MDR reports of individual adverse events within 30 days after the manufacturer becomes aware of a reportable death, serious injury, or malfunction as described in §§803.50 and 803.52.

(2) MDR reports of individual adverse events within 5 days of:

(i) Becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health or,

(ii) Becoming aware of an MDR reportable event for which FDA has made a written request, as described in §803.53.

(3) Annual baseline reports as described in §803.55.

(4) Supplemental reports if they obtain information that was not provided in an initial report as described in §803.56.

(5) Annual certification to FDA of the number of MDR reports filed during the preceding year as described in §803.57.

#### **§803.11 Obtaining the forms.**

User facilities and manufacturers must submit all reports of individual adverse events on FDA Form 3500A (MEDWATCH form) or in an electronic equivalent as approved under §803.14. This form and all other forms referenced in this section can also be obtained from the Consolidated Forms and Publications Office, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785, or from the Division of Small Manufacturers Assistance, Office of Health and Industry Programs, Center for Devices and Radiological Health, 1350 Piccard Dr. (HFZ-220), Rockville, MD 20850, telephone facsimile (FAX) 301-443-8818. FDA Form 3500A may also be obtained from the Food and Drug Administration, MEDWATCH (HF-2), 5600 Fishers Lane, rm. 9-57, Rockville, MD 20850, 301-443-0117.

#### **§803.12 Where to submit reports.**

(a) Any written report or additional information required under this part shall be submitted to: Food and Drug Administration, Center for Devices and